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EXAMINER	
HOLLINDEN, G	
ART UNIT	**PAPER NUMBER**
1209	4

DATE MAILED: 07/09/92

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☑ Responsive to communication filed on 5/7/92 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ___ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 4-5 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 4-5 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

This Office Action is a response to the amendment filed on May 7, 1992 wherein claims 1-3 were canceled, claim 5 was added and Group III was elected without traverse. Currently, Claims 4 and 5 are pending in this application and will be examined on their merits.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure. In particular, the amount of the protoporphyrin IX precursor which would be both safe and effective for the diagnosis of tissue abnormalities is not enabled. The specification fails to teach any range for diagnostic use (and in fact also fails to teach a range for therapeutic use). In addition, no examples of diagnostic use were taught. Particularly since the disclosure teaches that administration of said precursor can have toxic side effects (i.e. loss of motor nerve conduction), it would require undue experimentation to determine the diagnostic dosage which would be safe and effective.

Claims 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 4 and 5 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, claim 1 is rendered indefinite by the term "--effective amount--" since the specification fails to disclose what an effective amount would be.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 4 and 5 are rejected under 35 U.S.C. § 103 as being unpatentable over Blumberg et al. (A), Gordon (B), and Fukuda et al. (C).

These claims appear to be directed towards a method of administering a precursor of protoporphyrin IX (e.g. 5-aminolevulinic acid) for detection of tissue abnormalities.

Blumberg et al. (col 1, lines 57-69) teach that 5-aminolevulinic acid may be used to diagnose lead intoxication. Gordon (abstract and col 6 lines 51-67) and Fukuda et al. (col 6 lines 6-20) teach that various protoporphyrins are useful for the diagnosis of other tissue abnormalities (e.g. cancer).

While Blumberg et al. does not teach all of the claim designated skin abnormalities, it would have been obvious to those of ordinary skill in the art that the method of Blumberg et al. could be used for other skin diseases because Gordon and Fukuda et al. teach that the protoporphyrins are useful for the diagnosis of most of the claim designated tissue abnormalities.

The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure and shows the state of the art in its field but is not considered by the Examiner to read upon the invention currently being prosecuted in this application.

No Claim is allowed

The processing of this application can be expedited by providing the following information or changes in your next amendment:

- Proper cross-reference to related applications for which priority is claimed under 35 U.S.C. § 120 in the first paragraph of the specification - including current status (M.P.E.P. 201.11)
- Early filing of an Information Disclosure Statement that includes a PTO-1449 form wherein the document number, publication date, inventor, country of publication, and US patent classification is listed for each patent document and wherein the author, title, journal, volume, issue (if known), pages, and year of publication is listed for all journal references

(M.P.E.P. 609). A timely prior art disclosure by the Applicant aids in a speedy prosecution and helps to insure that the patent granted is both valid and enforceable.

- A descriptive title (M.P.E.P. 606 and 606.01). Please note that 1-2 word titles are generally unacceptable.
- An abstract which is descriptive of the disclosed invention and contains the structure of the active ingredient(s).
- Correction of any ambiguities in the specification which may lead to a printer inquiry, such as blank spaces which appear to be omissions.
- Correction of any typographical errors in the application.

Any inquiry concerning this Office Action or any earlier Office Actions from the Examiner should be directed to Dr. Gary E. Hollinden whose telephone number is 703/308-4521.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is 703/308-1235.

CAROLYN ELMORE
PRIMARY EXAMINER
GROUP 1200